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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/729,343 08/729343	10/16/96	LEE	D
CHOATE HALL & STEWART EXCHANGE PLACE 53 STATE STREET BOSTON MA 02109-2891			EXAMINER KULKOSKY, P ART UNIT PAPER NUMBER
HM12/0618			1615 DATE MAILED: 06/18/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on MARCH 08, 1999
- ☒ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire THREE month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-7, 9-16, 21-26 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-7, 9-16, 21-26 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 18
- ☐ Interview Summary, PTO-413
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Art Unit 1615

Claims 1-7, 9-16 and 21-26 are rejected under 35 U.S.C. § 103 as being unpatentable over Rey et al. Article and Eanes et al. Nature Article.

It is considered obvious for those skilled in the art to use a "poorly crystalline calcium phosphate in a method for treating a bone defect as claimed since the PCA material of the claims is known to the art and the use thereof for such a treatment requires only routine application of the known properties of said material.

The cited Prior Art does not teach away from the use of PCA calcium phosphate for a bone cement. The arguments of the Amendment are not fortified by scientific evidence or expert testimony. That is, it is expected that the calcium phosphate poorly crystalline materials of the references would function to yield results as described in the instant specification when applied by those skilled in the art in regard to bone defect treatments. If the "poorly crystalline apatitic calcium phosphate" of the claims differs from prior art materials disclosed in the cited Prior Art, it is incumbent upon the applicants to demonstrate an improved comparative result experimentally.

Claims 1-7, 9-16 and 21-26 are rejected under 35 U.S.C. § 103 as being unpatentable over Tung 5,037,639 or Chow et al. 5,542,973 each taken alone or together with Glimcher Article.

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The Applicants' Remarks have been carefully considered, but are not convincing in view of the fact that the claims do not define a calcium phosphate product which is distinguishable in physical description from the calcium phosphates of the references. The claims do not correspond to calcium phosphate bone treatment material products which are those of the instant specification working Examples. Resorption data of the materials of the cited Prior Art have not been compared experimentally as to closest embodiments of same. That is, the Applicants' arguments are not convincing in regard to maintaining that the cited Prior Art calcium phosphates are not resorbable over the range of the instant claims. It is suggested that the claims be limited to poorly crystalline calcium phosphate materials which have the physical identity of the working Example products or of the processes of the specification.

Claims 1-7, 9-16 and 21-26 are rejected under 35 U.S.C. § 112, paragraph 1.

The claims describe a "poorly crystalline" material and this term is not definitive of a particular structure which would be distinguishable from other forms of "poorly crystalline" calcium phosphate such as those of the Prior Art.

It is not clear from the specification whether the poorly crystalline calcium phosphates of the invention are necessarily prepared by a particular process such as that of the

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specification. That is, the specification does not state whether the preparation process is critical to obtaining a poorly crystalline calcium phosphate of improved properties.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

P. Kulkosky:cdc

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June 8, 1999



PETER F. KULKOSKY
PRIMARY EXAMINER